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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/708,919	03/31/2004	Mark C. Boomer	101896-0241	2918
21125 7590 08/24/2007 NUTTER MCCLENNEN & FISH LLP WORLD TRADE CENTER WEST 155 SEAPORT BOULEVARD BOSTON, MA 02210-2604			EXAMINER COMSTOCK, DAVID C	
			ART UNIT 3733	PAPER NUMBER
			MAIL DATE 08/24/2007	DELIVERY MODE PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/708,919	Applicant(s) BOOMER ET AL.	
	Examiner David Comstock	Art Unit 3733	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 08 June 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,2,7-10,13-20,42,43 and 46-50 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,2,7-10,13-20,42,43 and 46-50 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 31 March 2004 and 06 September 2005 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Drawings

The drawings are objected to because they are informal and are illegible due to poor print quality. Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 2, 7, 9, 13-16, 20, 42 and 43 are rejected under 35 U.S.C. 102(b) as being anticipated by Yue (6,007,536).

Yue discloses a device comprising a rod 1 that can be fixed at an angle with respect to a plate 2 by means of a fastening element 4 (see Figs. 1A-1C). The device adjusts in a single plane. The plate includes a female connector having arms that receive a male connector (see Fig. 1B). A bore extends through the male and female connector components to allow rotation about a cylindrical mating element attached to the female connector. The fastening element is mated with the female connector. Both the plate and rod are capable of being implanted and used for spinal applications.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1, 2, 13-20, 42, 43, 46, 48 and 49 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lai (5,509,328).

Lai discloses a device comprising a first elongate member 10 having a female connector with opposed arms 13 and a second elongate member 20 having a male connector 40 adapted to mate to the female connector (see Fig 2). The members are adjustably coupled to one another. A fastening element locks the elongate members in a fixed position. The devices are angularly adjustable in a single plane. The opposed arms define a recess for receiving the male connector. The device includes a bore 14

extending through the opposed arms on the female connector and through the male connector, and a central mating element 51,52 extending through the bore for mating the male and female connectors together. The central mating element comprises a cylindrical member 51. The device rotates about this member when it is in a loosened state. The cylindrical member is fixedly coupled to a portion of the female connector, and the male connector is free to rotate about the cylindrical member when loose. The fastening element is effective to engage the cylindrical member to prevent movement of the male connector relative to the female connector when tightened. The fastening element comprises a slot 43 extending through the male connector such that the male connector is in the form of a clamp, and wherein the device further comprises a threaded fastener 44 adapted to engage and mate with the male connector to clamp the cylindrical member within the bore. The female connector and male connector rotate about a central axis extending substantially perpendicular to an axis of the first and second elongate members. The fastening element is adapted to extend into a connector along an axis that is substantially parallel to the plane of adjustability. The diameter of the first and second elongate member appears to be substantially the same. A terminal end of the second elongate member is at an angle to a longitudinal axis of the second elongate member. Although the material of the device is not specified, it would have been obvious to have formed the device from, e.g., titanium, since it has been held to be within the general skill of a worker in the art to select a known material on the basis of its suitability for the intended use as a matter of obvious design choice.

In re Leshin, 125 USPQ 416. It is noted that titanium, among others, is a common material for devices of the type set forth by Lai and titanium is also biocompatible.

Claims 8, 10, 47 and 50 are rejected under 35 U.S.C. 103(a) as being unpatentable over Yue (6,007,536).

With regard to claim 8, Yue discloses the claimed invention except for disclosing that the device could be comprised of rods (or plates) instead of one rod and one plate. However, given the disclosure of both a rod and a plate, it would have been obvious to a person of ordinary skill in the art, to have configured the device with two rods (or plates) instead of one rod and one plate, in order to address the exigencies of surgical necessity or patient anatomy.

With regard to claims 10, 47 and 50, Yue discloses the claimed invention except for explicitly disclosing different diameters or an offset angle of 90 degrees. It would have been obvious to one having ordinary skill in the art at the time the invention was made to form the device with differing diameters or with an offset angle of 90 degrees, since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. *In re Aller*, 105 USPQ 233.

Response to Arguments

Applicant's arguments filed 08June 2007 have been fully considered but they are not persuasive.

Applicant's arguments regarding the biocompatibility of the device of Lai are moot in view of the new grounds of rejection necessitated by Applicant's amendment adding the limitation "biocompatible" to the claims.

With regard to Yue, the mating element is engaged such that the elongate members are locked in a fixed position, e.g., as about their pivot axis and in all but one plane, relative to one another. In addition, the device of Yue comprises a clamping mechanism at its terminal end at least because the device is rigid and is capable of receiving an object to be clamped between terminal ends thereof.

Finally, Examiner maintains and repeats by reference the response to arguments mailed 04 April 2007.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David Comstock whose telephone number is (571) 272-


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4710. Please leave a detailed voice message if examiner is unavailable. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Eduardo Robert can be reached at (571) 272-4719. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



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